

Notice of Allowability	Application No.	Applicant(s)	
	10/734,719	GILBERT ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Election of July 10, 2006.
2. ☒ The allowed claim(s) is/are 43,44,46 and 48-58.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>0706</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Applicant's election with traverse of Invention I in their response of July 10, 2006 is acknowledged. The traversal is on the following grounds. That, the polypeptides of SEQ ID NO: 12 and 14 have high homology to the polypeptide of SEQ ID NO: 9 and all polypeptides have the same activity. That, the subject matter of Claim 1 encompasses polynucleotides encoding SEQ ID NO: 12 and 14. That, the MPEP 803.04 states that ten sequences constitute a reasonable number of sequences to be search.

These grounds are found to be persuasive. It is acknowledged that SEQ ID NO: 12 and SEQ ID NO: 14 have 99.6% and 99.7% homology, respectively, to SEQ ID NO: 9 and as well as the same recited activity. Therefore, it is acknowledged that polynucleotides encoding SEQ ID NO: 12 or SEQ ID NO: 14 are encompassed within the subject matter of Claim 1. The restriction between the pending claims is withdrawn.

Examiner's note: Applicant is reminded that the MPEP 803.04 states **up to 10** distinct nucleotide sequences not **10** nucleotide sequences constitute a reasonable number.

Claims 43-58 are pending. Claims 43-58 encompass a single invention, directed to the polynucleotide of SEQ ID NO: 8 and variants thereof encoding polypeptides having α -2,3-sialyltransferase activity. Claims 43-58 are herein examined.

Priority

The priority date for SEQ ID NO: 8 and 9 is taken to be February 1, 1999, the filing date of US 60/118,212, while the priority date for SEQ ID NO: 11-14 is taken to be January 31, 2000, the filing date of US 09/495,406.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Specification

Replace the first paragraph of the specification with the following.

—This is a continuation application of and claims the benefit of U.S. Patent Application No. 09/816,028, filed March 21, 2001 and issued as US 6,699,705, which is a continuation-in-part of and claims the benefit of U.S. Application No. 09/495,406, filed January 31, 2000 and issued as 6,603,744, which claims the benefit of U.S. Provisional Application No. 60/118,213, which was filed on February 1, 1999; all three applications are incorporated herein by reference for all purposes.—

At page 4, line 22, delete: — (URL:<http://www.sanger.ac.uk/Projects/C.sub.--jejuni/>)—.

At page 5, line 3, delete: — URL:<http://www.cris.com/.about.ketchup/genedoc.sht-ml->.

At page 15, line 16, delete: — (<http://www.ncbi.nlm.nih.gov/>)—.

At page 42, line 3, delete: — (www.chem.qmw.ac.uk/iupac-/misc/glylp.html)—.

At page 53, line 16, delete: — (<http://www.sanger.ac.uk/Projects/C.sub.--jejuni/>)—.

At page 56, line 1, delete: —(URL:http://www.sanger.ac.uk/Projects/C_jejuni/)—.

Claims

Cancel Claims 45 and 47.

Replace Claims 43, 46, and 58 with the following:

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43. An isolated or recombinant nucleic acid molecule that comprises a polynucleotide sequence that encodes an α 2,3-sialyltransferase polypeptide, wherein the α 2,3-sialyltransferase polypeptide polypeptide is at least 90% identical to the polypeptide of SEQ ID NO: 9.

46. The nucleic acid molecule of claim 43, wherein the polynucleotide sequence that encodes the sialyltransferase polypeptide sequence is at least 90% identical to the polynucleotide of SEQ ID NO: 8.

58. An isolated or recombinant nucleic acid molecule that comprises a polynucleotide sequence that encodes a fusion protein comprising a sialyltransferase polypeptide and a tag for purification; wherein the sialyltransferase polypeptide has α 2,3-sialyltransferase activity; and wherein the sialyltransferase polypeptide is at least 90% identical to the polypeptide of SEQ ID NO: 9.

Amend Claims 49 and 52-57 as follows.

For Claim 49, replace –a nucleic acid molecule of claim 43– with –the nucleic acid molecule of claim 43–.

For Claim 52, replace –an amino acid sequence as set forth in SEQ ID NO: 9– with –the amino acid sequence as set forth in SEQ ID NO: 9–.

For Claim 53, replace –an amino acid sequence as set forth in SEQ ID NO: 12– with –the amino acid sequence as set forth in SEQ ID NO: 12–.

For Claim 54, replace –an amino acid sequence as set forth in SEQ ID NO: 14– with –the amino acid sequence as set forth in SEQ ID NO: 14–.

For Claim 55, replace –a nucleic acid sequence as set forth in SEQ ID NO: 8– with –the nucleic acid sequence as set forth in SEQ ID NO: 8–.

For Claim 56, replace –a nucleic acid sequence as set forth in SEQ ID NO: 12– with –the amino acid sequence as set forth in SEQ ID NO: 11–.

For Claim 57, replace –a nucleic acid sequence as set forth in SEQ ID NO: 14– with –the amino acid sequence as set forth in SEQ ID NO: 13–.

Authorization for this examiner's amendment was given in a telephone interview with Beth Kelly on August 30, 2006.

Allowable Subject Matter

Claims 43, 44, 46, and 48-58 are allowed.

The following is an examiner's statement of reasons for allowance.

Based on the following, the subject matter of Claims 43, 46, and 58 is enabled. Guo et al, 2004 teach that the percentage of random single-substitution mutations, which inactivate a protein, using a protein 3-methyladenine DNA glycosylase as a model, is 34% and that this number is consistent with other studies in other proteins (pg 9206, parag 4). Guo et al further show that the percentage of active mutants for multiple mutations appears to be exponentially related to this by the simple formula $(.66)^x \times 100\%$, where x is the number of mutations introduced (Table 1). Applying this estimate to the polypeptide of SEQ ID NO: 9, 90% identity allows up to 29 mutations within the 291 amino acids of said polypeptide. Thus, $(.66)^{29} \times 100\%$ or $5.8 \times 10^{-4}\%$ of random mutants having 90% identity would be active, e.g, 1 out of 171,090. Techniques known in the art, i.e., high throughput mutagenesis and screening techniques such as taught by Yeh et al, 1997, would allow for finding a few active mutants within several hundred thousand or up to about a million inactive mutants. Therefore, the skilled artisan is enabled to

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make and use polynucleotides encoding polypeptides having at least 90% identity with SEQ ID NO: 9 and having α 2,3-sialyltransferase activity.

All claims, Claims 43, 44, 46, and 48-58, are limited to an isolated or recombinant nucleic acid molecule comprising the polynucleotide of SEQ ID NO: 9, or variants thereof, wherein the polynucleotide molecule encodes a polypeptide having α 2,3-sialyltransferase activity. The specification asserts that the polypeptide encoded by SEQ ID NO: 9, as set forth by SEQ ID NO: 8, is an α 2,3-sialyltransferase (title and sequence listing). A utility for the polypeptide of SEQ ID NO: 8, as having α 2,3-sialyltransferase activity, is credible based on heterologous expression of the polypeptide and analysis by enzymatic assay (Table 5). The polynucleotides of SEQ ID NO: 11 and 13 encode the polypeptides of SEQ ID NO: 12 and 14, respectively. The polypeptides of SEQ ID NO: 12 and 14 have 99.6% and 99.7% homology, respectively, to SEQ ID NO: 8. Based on said homology, the skilled artisan would believe that, more likely than not, the polypeptides of SEQ ID NO: 12 and 14 also have α 2,3-sialyltransferase activity. The polynucleotides of SEQ ID NO: 9, 11, and 13 have use in the recombinant production of the encoded polypeptides. Moreover, the encoded α 2,3-sialyltransferases have real-world use in preparing the *C. jejuni* GT1a ganglioside mimic (Gilbert et al, 2000), and antibodies thereto, which can be used for investigating the mechanisms by which said ganglioside mimic affects neuro-muscular synaptic transmission (Goodyear et al, 1999).

Therefore, the polynucleotides of SEQ ID NO: 9, 11, and 13, as encoding the polypeptides of SEQ ID NO: 8, 12, and 14, have a specific and substantial patentable utility as encoding α 2,3-sialyltransferases.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
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SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER